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09/741,437	12/21/2000	Gregory S. Hamilton	23758	7495

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/741,437	<b>Applicant(s)</b> HAMILTON, GREGORY S.	
	<b>Examiner</b> Laura L. Stockton, Ph.D.	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 63-68 is/are pending in the application.  
     4a) Of the above claim(s) 67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 63-65 is/are rejected.
- 7) ☒ Claim(s) 4 and 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

**Claims 1-5 and 63-68 are pending in the application.**

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 21, 2003 has been entered.

### *Election/Restrictions*

Claims 67 and 68 are withdrawn as pertaining to a non-elected invention. See the Restriction Requirement dated July 26, 2001 {Paper No. 4} and Applicant's election dated August 22, 2001 {Paper No. 5}.

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Rejections made in the previous Office Action which do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,

6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming “active truncated derivatives thereof” in claim 5. The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instant specification does not give any guidance or definition as to what is meant by the expression “active truncated derivatives thereof”. The instant specification fails to give any guidance as to how the product is made. In order to practice the claimed invention, one skilled in the art would have to speculate Applicant’s intention for the

expression "active truncated derivatives thereof" found in instant claim 5 and speculate how the product is made. The number of possible "radicals" which could possibly be embraced by the claim would impose undue experimentation on the skilled art worker. Therefore, the expression "active truncated derivatives thereof" is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the expression "active truncated derivatives thereof" found in claim 5. Therefore, the metes and bounds of the claim cannot be ascertained since the instant specification fails to define the expression "active truncated derivatives thereof".

*Response to Arguments concerning 112 rejections*

Applicant's arguments filed July 25, 2003 have been fully considered. Applicant argues that the rejection of claim 5 under 35 USC 112, first and second paragraphs is improper and should be withdrawn as there is absolutely no requirement that any applicant define any term whatsoever. In response, the Examiner disagrees. 35 U.S.C. § 112, first paragraph states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention". Applicant has not defined what is meant by the expression "active truncated derivatives thereof" and the instant specification fails to teach how an "active truncated derivative" is prepared.

Applicant argues that the expression was not questioned in other patents. Applicants argues that ascertaining the meaning of "active



truncated derivatives thereof” is within the level of ordinary skill in the art. Applicant argues that claim 5 is sufficient to satisfy the statutory requirement under 35 USC 112, second paragraph if one of ordinary skill in the art would understand the bounds of the claim when read in light of the specification.

All of Applicant’s arguments have been considered but have not been found persuasive. The specification should disclose every aspect of Applicant’s invention. The instant specification fails to define what is meant by “active truncated derivatives thereof”. Applicant has failed to specify in their remarks where in the instant specification (page and line numbers) the expression “active truncated derivatives thereof” is defined. Although Applicant argues that the expression is within the level of ordinary skill in the art, it is noted that Applicant has not provided the Office with a definition of “active truncated derivative thereof”. Since it is unclear what is meant by the expression “active truncated derivatives thereof” found in claim 5, claim 5 is indefinite because the metes and

bounds of the claim cannot be ascertained. The rejections are deemed proper and are maintained.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1,503,244 .

The GB reference disclose, for instance, Example 1(A) in water (page 6) that is embraced by the instant claims.

*Response to Arguments concerning 102(b) rejections*

Applicant's arguments filed July 25, 2003 have been fully considered. Applicant argues that GB 1,503,244 does not anticipate the instant claims since the GB patent describes a fungicide or herbicide but never anticipates any composition comprising a "pharmaceutically acceptable carrier".

In response, GB 1,503,244 does teach carriers (page 17, lines 39-44), such as alcohols, kaolin, talc, etc., that are known in the pharmaceutical art as pharmaceutically acceptable carriers. See, for example, Jamieson et al., column 3, lines 24-68 and column 4, lines 1-16. Further, Example 1(A) on page 6 is in water (e.g., a pharmaceutically acceptable carrier). See, for example, Bender {U.S. Pat. 4,186,205}, column 4, lines 6-14 also for known pharmaceutically acceptable carriers.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakabayashi et al. {JP 52-083686}, GB 1,503,244 and Jamieson et al. {U.S. Pat. 4,230,709}, each taken alone or in combination with each other when similar utilities are asserted. An English translation of JP 52-083686 has been supplied with a previous Office Action and will be referred to hereinafter.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicant claims hydantoin products. Wakabayashi et al. {page 3 and Table I on pages 9-13}, GB 1,503,244 {page 2, Formula I ; Table I pages 8-11; page 17, lines 39-44; and Example 1(A) page 6} and Jamieson et al. {column 1, Formula I; column 3, lines 24-68; column 4, lines 1-16; and Examples 6 and 8 in column 5} each teach hydantoin

products which are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed products.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between some of the products in the prior art and the products instantly claimed is that the prior art generically describes the instantly claimed products.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating asthma).

One skilled in the art would thus be motivated to prepare compounds embraced by the reference genera to arrive at the instant claimed products with the expectation of obtaining compounds which would be useful in treating, for example, asthma. The instant claimed invention would have been suggested to one skilled in the art and

therefore, the instant invention would have been obvious to one skilled in the art.

*Response to Arguments concerning 103 rejections*

Applicant's arguments filed July 25, 2003 have been fully considered. Applicant argues that: (1) the rejection is improper and should be withdrawn; (2) the fact pattern in the instant case differs from that in *In re Lemin* since "indiscriminately" selecting an embodiment of the claimed invention would not necessarily produce any compound from the generic disclosure of Wakabayashi et al, GB 1,403,244 or Jamieson et al.; (3) the record and explanation lack the required motivation and expectation of success for modifying GB 1,503,244; and (4) even if GB 1,503,244 were to teach an isomer of any claimed invention, that alone would not be enough to render that claim *prima facie* obvious since isomers having the same empirical formula but different structures are not necessarily considered equivalents by chemists skilled in the art.

All of Applicants' arguments have been considered but have not been found persuasive. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

In the instant application, Applicant claims hydantoin compounds and compositions. Wakabayashi et al. {page 3 and Table 1 on pages 9-13}, GB 1,503,244 {page 2, Formula I; Table 1 pages 8-11; page 17, lines 39-44; and Example 1(A) page 6} and Jamieson et al. {column 1, Formula I; column 3, lines 24-68; column 4, lines 1-16; and Examples 6 and 8 in column 5} each teach hydantoin compounds and compositions which are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed products.

The difference between some of the products in the prior art and the products instantly claimed is that the prior art generically describes the instantly claimed products.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating asthma).

One skilled in the art would thus be motivated to prepare compounds embraced by the reference genera to arrive at the instant claimed products with the expectation of obtaining compounds which would be useful in treating, for example, asthma. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant invention would have been obvious to one skilled in the art.

Applicant argues that the fact pattern in *In re Lemin* vastly differs from the instant case since "indiscriminately" selecting an embodiment of the claimed invention would not necessarily produce any compound from



the generic disclosure of Wakabayashi et al, GB 1,403,244 or Jamieson et al. The Examiner disagrees. A comparison is made of the products disclosed in GB 1,503,244 and the third compound listed in instant claim 2 (instant claim 2 is a compound claim). Example 1(A) on page 6 of the GB patent is 3-(3'-trifluoromethyl-phenyl) 1,5-trimethylenehydantoin whereas the third compound listed in instant claim 2 is a (7aS)-2-(4-(trifluoromethyl)phenyl)perhydropyrrolo[1,2-c]imidazole-1,3-dione. The only difference in the two products is the position of the trifluoromethyl group on the phenyl ring (e.g., 3-CF<sub>3</sub> in the GB versus 4-CF<sub>3</sub> instantly claimed). However, the GB teaches (Formula I on page 2) that substitution can be present in any position on the phenyl ring to have the desired activity. Note the 4-position substitutions on the phenyl ring in compound numbers 2-7 on page 8 of the GB patent. Therefore, "indiscriminately" selecting an embodiment of the claimed invention would produce a compound from the generic disclosure of the GB patent.

A comparison is made between the generic disclosure in Jamieson et al. (column 1, lines 20-54) and instant claim 3 (instant claim 3 is a composition claim). The products of Jamieson et al. are embraced by the instant claim wherein  $R^1$  and  $R^4$  are taken together represent a  $C_3$  alkylene,  $R^2$  is hydrogen and  $R^3$  is benzyl. Jamieson et al. also prepare Examples 6 and 8 and teaches pharmaceutical formulations (column 3, lines 55-68; and column 4, lines 1-16) which are useful in treating asthma. Therefore, "indiscriminately" selecting an embodiment of the claimed invention would produce a compound from the generic disclosure of Jamieson et al.

A comparison is made of the products disclosed in Wakabayashi et al. and the third compound listed in instant claim 2 (instant claim 2 is a compound claim). Compound No. 1 on page 9 of Wakabayashi et al. is 3-(3'-trifluoromethyl-phenyl)1,5-trimethylenehydantoin whereas the third compound listed in instant claim 2 is a (7aS)-2-(4-(trifluoromethyl)phenyl)perhydropyrrolo[1,2-c]imidazole-1,3-dione. The only difference in the two products is the position of the trifluoromethyl

group on the phenyl ring (e.g., 3-CF<sub>3</sub> in Wakabayashi et al. versus 4-CF<sub>3</sub> in the instant claimed compound). However, Wakabayashi et al. teach (the formula I on page 3) that substitution can be present in any position on the phenyl ring to have the desired activity. Note the 4-position substitutions on the phenyl ring in compound numbers 2-8 on page 9 of Wakabayashi et al. Therefore, "indiscriminately" selecting an embodiment of the claimed invention would produce a compound from the generic disclosure of Wakabayashi et al.

Therefore, the prior art references do suggest the instant claimed invention and would motivate one skilled in the art to prepare additional products embraced by the prior art with the expectation of obtaining products that would have, for example, fungicidal activity or would be useful in treating asthma. For all the reasons given above, the rejection is proper and is maintained.

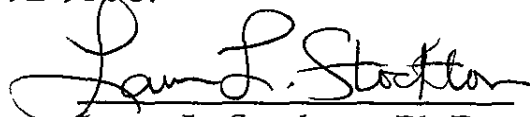
*Allowable Subject Matter*

Claims 4 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable over the art of record if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

January 2, 2004